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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Ulrich Sieben

Mic.7776

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7590

12/10/2008

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SPRINGFIELD, MA 01115

EXAMINER

WALTERS JR, ROBERT S

ART UNIT

PAPER NUMBER

1792

MAIL DATE

DELIVERY MODE

12/10/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/511,192	<b>Applicant(s)</b> SIEBEN ET AL.	
	<b>Examiner</b> ROBERT S. WALTERS JR	<b>Art Unit</b> 1792	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-12, 14 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-12, 14 and 16-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/23/2008</u> .                                               | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Application***

Claims 2-12, 14, and 16-21 are pending and presented for examination.

### ***Response to Arguments***

Applicant's arguments with respect to claims 2-12, 14, and 16-21 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 recites the limitation "molecules". There is insufficient antecedent basis for this limitation in the claim. Claim 5 should actually recite UV-reactive *biomolecules* as the currently amended claim 8 requires that the molecules be biomolecules.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3, 6, 8, 11, 12, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Matson (U.S. PGPUB No. 2003/0198968).

Regarding claims 3, 6, 8, 11, 12, and 17, Matson teaches a method for immobilizing biomolecules on a substrate by applying a layer of polymer to the surface and immobilizing the biomolecules on the surface of the polymer layer (abstract). Matson further teaches that the polymeric layer may be hydrophobic (0018) and that the biomolecules may be applied by spotting (0095). Matson also teaches that the substrate may be an inorganic material (0042), that the polymeric layer can be activated by an oxygen plasma treatment (0070), and that the hydrophobic polymer can be applied in defined regions to provide hydrophobic sections and other sections that are not hydrophobic (0073).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 5, 9, 10, 16, and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matson in view of Wybourne et al. (U.S. Pat. No. 5465151).

Regarding claims 2, 5, 9, 10, 16, and 18-20, Matson teaches all the limitations of claim 8 and 17, but fails to teach the polymer being polyimide, polystyrene, or a non-swelling polymer and fails to teach the substrate surface being a material from the group claimed. Matson further fails to teach using UV light to immobilize the molecules. Wybourne teaches a method for

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making biosensors capable of immobilizing biomolecules (abstract), wherein the biosensor has a surface, such as a semiconducting silicon dioxide, and that a polymeric material is applied over this surface, the polymeric material potentially being polystyrene, polyimide or poly(ethylenes), which are non-swelling (see Table 1, column 10 and column 10, lines 46-48). Wybourne further teaches that UV light can be used to functionalize or immobilize molecules on the polymer (column 13, lines 19-28). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Matson's method by utilizing semiconducting silicon dioxide as a substrate and polystyrene, polyimide, or polyethylene as the polymeric material to bind to biomolecules, with the binding accomplishable by utilizing UV light, as taught by Wybourne. One would have been motivated to make this modification as one of ordinary skill could have chosen to utilize these substrates, polymeric materials, and UV activation in Matson's method with a reasonable expectation of success and a predictable result, given that these elements are also being applied in Wybourne's method to immobilize biomolecules.

Claims 4 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matson in view of Sheu et al. (U.S. Pat. No. 5700559).

Regarding claims 4 and 14, Matson teaches all the limitations of 8, and teaches activating the polymeric layer by plasma treatment, but fails to explicitly teach imparting an electric charge to the surface of the polymer layer. Sheu teaches a process of imparting a charge to a surface of a polymer by plasma treatment (column 6, lines 28-33) to activate it for binding of another layer (column 1, lines 39-44). It would have been obvious to one of ordinary skill in the art at the time

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of the invention to modify Matson's method by imparting a charge to the polymer surface by a plasma treatment, as taught by Sheu. One would have been motivated to make this modification as it would potentially allow binding of hydrophilic or charged biomolecules to the surface of a hydrophobic polymer, which would likely not be possible without the surface of the hydrophobic polymer being charged.

Claims 7 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matson in view of Heller et al. (U.S. Pat. No. 6560471).

Regarding claims 7 and 21, Matson teaches all the limitations of claim 8, but fails to teach the polymeric layer being integrated into an integrated circuit or on a support in which electrical sensors and processor circuits are integrated. Heller teaches the fabrication of an analyte sensor (abstract). The sensor comprises a substrate which has a sensing layer (Figure 2) disposed thereon. The sensing layer contains immobilized compounds such as catalysts (column 16, lines 12-18), which are immobilized, for example, by entrapping within a polymeric matrix (column 16, lines 25-29). The polymer layer itself is disposed on the electrode on the substrate (column 8, lines 1-6). Therefore the sensing layer is formed directly on an electrode at the tip of the sensor (column 16 lines 6-8) and electric sensors are integrated in the surface onto which the molecules are immobilized.

The sensor is also integrated with the sensor control unit in Figures 18A and 18B, which includes processing circuits (109 in Figures 18A and 18B). Further, the substrate and immobilized sensing layer are a part of an integrated circuit in the embodiment of Fig 32

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(column 33, lines 10-21). In one example, the compound which is immobilized within the sensing layer is an enzyme, which is a type of biomolecule (column 17, lines 24-27).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Matson's method by applying it as the polymeric matrix in Heller's electronics. One would have been motivated to make this modification, as this modification would allow for in-vivo monitoring of biomolecules or other agents in patients (see Heller at column 1, lines 6-11).

Claims 2, 5, 8-10, and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wybourne in view of Matson et al. (U.S. PG PUB No. 2001/0039018, hereinafter referred to as Matson2).

Regarding claims 2, 5, 8-10, and 16-20, Wybourne teaches a method for making biosensors capable of immobilizing biomolecules (abstract), wherein the biosensor has a surface, such as a semiconducting silicon dioxide, and that a polymeric material is applied over this surface, the polymeric material potentially being polystyrene, polyimide or poly(ethylenes), which are non-swelling (see Table 1, column 10 and column 10, lines 46-48). Wybourne further teaches that UV light can be used to functionalize or immobilize molecules on the polymer (column 13, lines 19-28). Wybourne fails to teach immobilizing the molecules by spotting. Matson2 teaches that spotting is a well known means of applying biomolecules to a support (0062). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Wybourne's method by applying the biomolecules by spotting, as taught by Matson2. One would have been motivated to make this modification as this is a well known method of



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specifically applying a biomolecule to a substrate and one of ordinary skill in the art at the time of the invention could have utilized this approach to attach the biomolecules in Wybourne's method with a reasonable expectation of success and a predictable result.

Claims 3, 4, 6, 11, 12, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wybourne in view of Matson2 as applied to claim 8 above, and further in view of Sheu.

Regarding claims 3, 4, 6, 11, 12, and 14, Wybourne in view of Matson2 teach all the limitations of claim 8, but fail teach the plasma treatment or the application of the polymer in defined regions. Sheu teaches a process of imparting a charge to a surface of a polymer by plasma treatment (column 6, lines 28-33), and specifically oxygen plasma treatment (column 6, lines 42-43), to activate it for binding of another layer (column 1, lines 39-44). Sheu further teaches that the polymeric layer can be applied to the surface in formed defined regions (column 3, lines 35-40). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Wybourne in view of Matson2's method by imparting a charge to the polymer surface (that has been applied in defined regions) by a plasma treatment, as taught by Sheu. One would have been motivated to make this modification as it would potentially allow binding of hydrophilic or charged biomolecules to the surface of a hydrophobic polymer, which would likely not be possible without the surface of the hydrophobic polymer being charged.

Claims 7 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wybourne in view of Matson2 as applied to claim 8 above, and further in view of Heller.

Regarding claims 7 and 21, Wybourne in view of Matson2 teach all the limitations of claim 8, but fail to teach the polymeric layer being integrated into an integrated circuit or on a support in which electrical sensors and processor circuits are integrated. Heller teaches the fabrication of an analyte sensor (abstract). The sensor comprises a substrate which has a sensing layer (Figure 2) disposed thereon. The sensing layer contains immobilized compounds such as catalysts (column 16, lines 12-18), which are immobilized, for example, by entrapping within a polymeric matrix (column 16, lines 25-29). The polymer layer itself is disposed on the electrode on the substrate (column 8, lines 1-6). Therefore the sensing layer is formed directly on an electrode at the tip of the sensor (column 16 lines 6-8) and electric sensors are integrated in the surface onto which the molecules are immobilized.

The sensor is also integrated with the sensor control unit in Figures 18A and 18B, which includes processing circuits (109 in Figures 18A and 18B). Further, the substrate and immobilized sensing layer are a part of an integrated circuit in the embodiment of Fig 32 (column 33, lines 10-21). In one example, the compound which is immobilized within the sensing layer is an enzyme, which is a type of biomolecule (column 17, lines 24-27).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Wybourne in view of Matson2's method by applying it as the polymeric matrix in Heller's electronics. One would have been motivated to make this modification, as this modification would allow for in-vivo monitoring of biomolecules or other agents in patients (see Heller at column 1, lines 6-11).

***Conclusion***

Claims 2-12, 14, and 16-21 are pending.

Claims 2-12, 14, and 16-21 are rejected.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT S. WALTERS JR whose telephone number is (571)270-5351. The examiner can normally be reached on Monday-Thursday, 6:30am to 5:00pm EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Barr can be reached on (571)272-1414. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ROBERT S. WALTERS JR/  
December 8, 2008  
Examiner, Art Unit 1792

/Michael Barr/  
Supervisory Patent Examiner, Art Unit  
1792

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